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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,733	08/17/2001	Ulrich Certa	20676	4620

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 HOFFMANN-LA ROCHE INC.
 PATENT LAW DEPARTMENT
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EXAMINER

HOLLERAN, ANNE L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/931,733	Applicant(s) CERTA, ULRICH	
	Examiner Anne Holleran	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 8-10 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11-13 and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The amendment filed January 7, 2004 is acknowledged. Claim 21 was canceled.

Election/Restrictions

2. Applicant's election with traverse of group I and species S75415 in the paper filed Jan. 7, 2004 is acknowledged. The traversal is on the ground(s) that the product claims of groups III and IV should not be restricted from groups I and II, respectively, because the products of groups III and IV are drawn to diagnostic kits that are to be used in the claimed methods. This is not found persuasive because the claimed inventions are product claims with an intended use limitation that does not limit the claimed products to what would only be useful in the claimed methods. As discussed in the previous Office action, inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the inventions of group III may be used in the materially different process from the methods of group I, where the other method is that of making a polypeptide; and the antibody of invention IV may be used in a materially different process from the methods of group II, where the other method is that of isolating and purifying an antigen.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-20 are pending.

Claims 8-10 and 14, drawn to non-elected inventions, are withdrawn from consideration.

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Claims 1-7, 11-13 and 15-21 (to the extent that the claims read on methods of detection of nucleic acids) are examined on the merits.

Claim Rejections Withdrawn:

4. The rejection of claims 1-7, 11-13 and 15-21 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn. However, see new grounds of rejection.

5. The rejection of claims 1-7 and 15-21 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art, that the inventor(s) at the time the application was filed, had possession of the claimed invention. The basis of this rejection is that for claims 1-6, the specification lacks adequate description of the genus of "genes predictive for" a treatment; in the case of claims 4-6 and 7, the specification lacks an adequate description of the genus of "genes predictive for IFN- α treatment"; and in the case of claims 15-21, the specification lacks an adequate description of the genus of "genes predictive for IFN- α treatment" and also lacks an adequate description of the genes designated as "S75415, M32053, X16665 and D00597" is withdrawn. However, see new grounds of rejection.

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6. The rejection of claims 1, 2, 6, 7, and 11 under 35 U.S.C. 102(b) as being anticipated by Johnston (Johnston, P.G. et al., Cancer Res., 55: 1407-1412, 1995; cited in the IDS) is withdrawn in view of the amendment.

7. The rejection of claims 1, 2, 4-7, and 11-13, 15, 17, 19 and 20 under 35 U.S.C. 102(a) as being anticipated by Celis (Celis, J.E. et al., FEBS Letters., 480: 2-16, 2000; 25 August; cited in the IDS) is withdrawn in view of the amendment.

8. The rejection of claims 1-3, 6, 7, and 11-13 under 35 U.S.C. 102(b) as being anticipated by Scherf (Scherf, U. et al., Nature Genetics, 24: 236-244, 2000; March; cited in the IDS) is withdrawn in view of the amendment.

Scherf teaches detecting sensitivity to therapy in melanoma cell lines (see page 241, 2nd col. and Figure 2, legend). Thus, Scherf teaches methods that are the same as that claimed.

Claim Rejections Maintained:

9. The rejection of claims 1, 2, 4-7, 11-13, 15, 17, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Silverman (U.S. Patent 6,331,396; issued Dec. 18, 2001; effective filing date Sep. 23, 1998) is maintained.

Silverman teaches methods for establishing patient sensitivity to IFN- α (see col. 3, lines 8-22; col. 7, lines 20-41), where the methods comprise measuring the mRNA expression level of genes (see col. 3, line 65- col. 5, line 30). Thus, Silverman teaches methods that are the same as that claimed.

Applicant argues that Silverman fails to teach methods comprising the measurement of a gene having the nucleic acid sequence of SEQ ID NO: 1. However, applicant states that S75415 (now referred to as SEQ ID NO: 1) is the nucleic acid sequence of the IFI16 gene. Silverman teaches a Table of possible genes that may be monitored and lists IFI 16, which appears to be the same gene (see Table 2, cols. 15-16). Thus, the rejection is maintained.

10. The rejection of claims 11-13 under 35 U.S.C. 102(b) as being anticipated by Der (Der, S. D. et al., Proc. Natl. Acad. Sci, USA, 95: 15623-15628, 1998; cited in the IDS) is maintained.

Claims 1-13 are drawn to methods comprising the identification of gene expression profiles in cell lines or tumor cell lines. Der teaches the identification of gene expression profiles in HT1080 cell lines, comprising the use of oligonucleotide probes. Thus, Der teaches methods that are the same as that claimed.

Applicant argues that Der fails to teach methods comprising the measurement of a gene having the nucleic acid sequence of SEQ ID NO: 1. However, applicant states that S75415 (now referred to as SEQ ID NO: 1) is the nucleic acid sequence of the IFI16 gene. Der teaches a Table of possible genes that may be monitored and lists IFI 16, which appears to be the same gene (see Table 2, page 15625). Thus, the rejection is maintained.

New Grounds of Rejection:

11. Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 11 is indefinite because the phrase "said gene express profiles" in line 4 lacks antecedent basis.

12. Claims 1-7, 11-13 and 15-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The basis for this rejection is that the amendment adding the limitation that the genes levels to be measured are selected from the group consisting of nucleic acids having SEQ ID NOs: 1, 3, 4 and 6 introduces new matter into the specification.

Applicant has argued that the amendment to the specification and to the claims, where the added material is that of the sequences of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3 and SEQ ID NO: 4, does not introduce new matter into the specification because these sequences were previously described in terms of references to NCBI accession numbers, S75415, M32053, X16665 and D00597 (even though one of the accession numbers, D00597 contained a typographical error) in the claims. Additionally, the four genes that corresponded to these accession numbers were referred to by name, IFI16, H19, RCC1 and hox2 in the specification (although the specification failed to teach the specific names of the genes with specific reference to the NCBI accession numbers). This argument is not found persuasive because the information associated with NCBI accession numbers may be updated at any time, and a claim that references an NCBI accession number is referring to a product, the structure of which may

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change with time, depending on whether the information in the database is updated. Therefore, referring to an NCBI accession number does not confine applicant to that which was invented at the time of filing.

13. The amendment filed January 7, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendment to paragraph 0014, which adds nucleic acid and protein amino acid sequences (SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3 and SEQ ID NO: 4) to the specification and also which changes the accession number "D00597" to "D00591".

Applicant is required to cancel the new matter in the reply to this Office Action.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D. can be reached at (571) 272-0871.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
April 4, 2004


MARY KUNZ
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